Remarks

Claims 1-16, 18, and 20-31 are pending, claims 20-30 have been withdrawn and claim 17 has been cancelled. Claims 1, 18, and 31 have been amended. Support for the amendments to the claims can be found in general throughout the above-captioned application, and in particular, for example, as follows: claim 1, Examples 1, 4 and 5, and claim 31, Example 5 and page 4, lines 16-18. No new matter has been added. Applicants reserve the right to prosecute both the amended claims in their original form and the cancelled claims in a continuing application.

Claims 1, 3-10, 13, 15, 18 and 31 stand rejected under 35 U.S.C. § 103 over U.S. Patent 6,299,925 (Xiong et al.)

Xiong et al. disclose a water soluble formulation in a granular or tablet form that includes from about 10 % by weight to about 50 % by weight green tea extract (Xiong et al., col. 3, lines 4-7). The formulation can optionally include extracts from other plants such as herbal plants, fruits and vegetables (*Id.*, lines 7-10). Xiong et al. also disclose that the formulations can include sodium bicarbonate and citric acid.

Claim 1 is now directed to a tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent that includes an acid and a base, binder, and lubricant, and that disintegrates in water having a temperature of about 22° C in less than 2.5 minutes to a solution that is free of granules and particles. In order to establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all of the claim limitations." M.P.E.P. 2142. As a preliminary matter, Xiong et al. do not teach or suggest including at least 200 mg cranberry extract in an effervescent composition and nothing in the record establishes anything to the contrary. For this reason alone, the rejection of claim 1 under 35 U.S.C. § 103 over Xiong et al. cannot be maintained and must be withdrawn.

Moreover, nothing in Xiong et al. teaches or suggests that the amount of cranberry extract is an important variable to be optimized. To assert anything to the contrary is to engage in impermissible hindsight reconstruction. Xiong et al. list fruit extracts as one of a number of optional components that can be included in their green tea formulation (see, Xiong et al., col. 5, line 50). In a separate section Xiong et al list more than thirty fruit extracts, only one of which is cranberry (see, *Id.*, Example VII). Nothing

in Xiong et al. specifically directs the skilled artisan to select cranberry extract from this list of fruit extracts. Moreover, although Xiong et al. disclose that their composition can include from 5 % to 50 % by weight fruit extract, Xiong et al. do not teach or suggest an actual weight of cranberry extract that should be included in their composition –let alone including at least 200 mg cranberry extract in an effervescent composition. Thus, to attempt to arrive at the tablet of claim 1 from Xiong et al. the skilled artisan would have to make a series of selections. In particular, the skilled artisan would have to 1) decide to modify Xiong et al.'s green tea formulation of Example VII, when Xiong et al. provide eight different formulations, 2) select cranberry extract from the more than thirty fruit extracts listed by Xiong et al. when Xiong et al. do not ascribe any particular significance to cranberry extract, 3) decide to include at least 200 mg cranberry extract when Xiong et al. do not teach or suggest that the composition should include any particular mass of cranberry extract but instead disclose a broad range of weight percents based on the entire formulation, and 4) decide to formulate the resulting composition as a tablet, when Xiong et al. do not teach or suggest how to successfully incorporate at least 200 mg of cranberry extract in a tablet. Nothing in Xiong et al. provides the requisite direction to the skilled artisan to make these specific selections.

Xiong et al. also do not to teach or suggest an effervescent tablet that includes at least 200 mg cranberry extract and disintegrates in water to form a solution that is free of granules and particles. Applicants' Specification demonstrates that not all extracts of cranberry can be formulated into an effervescent tablet (see, e.g., Applicants' Specification, Example 2, page 10, lines 13-26). Applicants' Specification further demonstrates that not all extracts of cranberry can be formulated into an effervescent tablet that dissolves in water to form a solution that is free of granules and particles (see, e.g., *Id.*, Example 2, page 10, lines 13-26). Xiong et al. do not teach or suggest how to achieve the tablet of claim 1. Therefore, the skilled artisan would have no clue as to how to do so. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Xiong et al. cannot stand and respectfully request that it be withdrawn.

The May 15, 2007 Office action takes the position, "The amount of a specific ingredient in a composition and the physical characteristics of the tablet are clearly result effective parameters that a person of ordinary skill in the art would routinely optimize."

Id. It is well established by legal precedent that "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." M.P.E.P. 2144.05. In addition, the case law that has developed around result-effective variables pertains to situations in which a composition is otherwise disclosed in a reference but the particular claimed range of a component or property of the composition is not expressly taught by the reference. Xiong et al. do not teach an effervescent tablet having a composition within which the composition of the tablet of claim 1 falls. In particular, Xiong et al. do not teach an actual composition that includes cranberry extract or that disintegrates in water in any particular period of time. Xiong et al. also do not teach or suggest that the amount of cranberry extract in an effervescent composition is a result effective variable. Rather, Xiong et al. disclose that their composition can include extracts of fruit among a list of other classes of extracts including plants and vegetables. In a separate area of the patent Xiong et al. list a number of fruits from which extracts can be obtained including, e.g., apple, apricot, banana, blue berry, cranberry, cherry, fig, grape, grapefruit, kiwi, lemon, lime, peach, pear, pineapple, orange, papaya, strawberry, tangerine and watermelon (see, Xiong et al., Example 7). Nothing in the two passages from Xiong et al. highlights cranberry extract or specifies a particular amount of cranberry extract. As such, the determination of the amount of cranberry extract in a tablet cannot be deemed to be a matter of routine experimentation. Accordingly, the result-effective variable theory is inapplicable to the patentability of claim 1. For at least this additional reason, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 103 over Xiong et al. is unwarranted and respectfully request that it be withdrawn.

Claims 2-10, 13, 15, 16 and 18 are distinguishable under 35 U.S.C. § 103 over Xiong et al. for at least the same reasons as set forth above with respect to claim 1.

Claim 16 is further distinguishable under 35 U.S.C. § 103 over Xiong et al. for at least the following additional reasons. Claim 16 is directed to a tablet that includes an effervescent composition that includes from 50 mg to 200 mg cranberry seed oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 5 kilopounds and disintegrating in water in less than 2.5 minutes. Nowhere in Xiong et

al. is there a teaching or a suggestion of cranberry seed oil –let alone including from 50 mg to 200 mg cranberry seed oil in an effervescent composition. Rather, Xiong et al. only disclose that their formulations can include fruit extract (see, Xiong et al., col. 3, lines 7-10, and Example 7). At no point do Xiong et al. teach or suggest that the fruit extract can be cranberry seed oil. As such, Xiong et al. fail to teach or suggest each and every element of claim 16. Accordingly, a *prima facie* case of the obviousness of claim 16 has not been made and the rejection of claim 16 under 35 U.S.C. § 103 over Xiong et al. cannot stand. Should this rejection be maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Xiong et al. of a teaching of cranberry seed oil.

Claim 31 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent that includes an acid and a base, binder, and lubricant, the binder being present in the composition in amount of from about 15 % by weight to about 50 % by weight, and the tablet being free of picking, capping, die wall etching and lamination. Xiong et al. do not teach or suggest including from about 15 % by weight to about 50 % by weight binder in an effervescent tablet --let alone including from about 15 % by weight to about 50 % by weight binder in an effervescent tablet that also includes 200 mg cranberry extract. Xiong et al. disclose that polyvinyl pyrrolidone is one example of a binder. In each of the Example formulations of Xiong et al. the range of polyvinyl pyrrolidone is indicated as being from 1 to 10 (%w/w). Nowhere in Xiong et al. is there a teaching of including from about 15 % by weight to about 50 % by weight binder in an effervescent tablet. Accordingly, Xiong et al. fail to teach or suggest a required element of claim 31; Consequently a *prima facie* case of obviousness has not been made. As such, the rejection of claim 31 under 35 U.S.C. § 103 over Xiong et al. cannot stand and must be withdrawn.

Claims 11, 12, and 14 stand rejected under 35 U.S.C. § 103 over Xiong et al. as applied to claims 1, 3-10, 13, 15, 18 and 31 above, and further in view of U.S. Patent Publication No. 2003/0161875 (Murpani et al.)

The discussion of Xiong et al. set forth above is incorporate herein by reference.

Murpani et al. disclose tablets that disintegrate and dissolve in the oral cavity without the need of water (Murpani et al., para. [0007]). The tablets of Murpani et al. include a therapeutically effective amount of drug that acts as COX-2 inhibitors (*Id.*). Murpani et al. also disclose a long list of almost thirty optional fillers that can be added to the composition including aluminum magnesium hydroxide and sorbitol (*Id.*, para. [0024]). The optional fillers are selected to give bulk to the COX-2 composition and are physically and chemically compatible with a COX-2 inhibitor (*Id.*).

Claim 11 depends from claim 1 and specifies that the effervescent agent includes sodium bicarbonate and citric and that the tablet further includes polyethylene glycol, sorbitol and sodium benzoate. The discussion of the deficiencies of Xiong et al. set forth above, are incorporated herein. As established above with respect to claim 1, Xiong et al. fail to teach or suggest a tablet that includes an effervescent composition that includes at least 200 milligrams of cranberry extract. It is also undisputed that Xiong et al. do not mention sorbitol.

Murpani et al. do not cure the deficiencies of Xiong et al. Murpani et al. do not teach or suggest anything about cranberry extract or the amount of cranberry extract to include in an effervescent composition. Murpani et al. also do not teach or suggest combining sorbitol with a green tea extract such as the one disclosed in Xiong et al. Moreover, the skilled artisan is not an automaton (see, *KSR Int'l Co. v. Teleflex Inc.*, 500 U.S. _____, 82 U.S.P.Q.2d 1385 (2007)). The technology described in Murpani et al. is directed to tablets that do not have to be dissolved in water. Murpani et al. expressly state that an object of their invention is to provide a fast dissolving tablet that disintegrates quickly in the mouth without the need for additional water (Murpani et al., page 1, para. [0007]). Murpani et al. further disclose that many elderly persons have difficulty in taking oral dosage forms such as solutions, suspensions, tablets and capsules because of hand tremors and dysphasia (*Id.*, page 1, para. [0005]). Murpani et al then disclose that the increase in intake of water for swallowing conventional dosage forms results in frequent urination and nocturia (*Id.*). Murpani et al. also note that swallowing problems are also common in mentally ill, the developmentally disabled, and patients who are uncooperative, on reduced liquid-intake plans or are nauseated (*Id.*, para. [0006]). Thus, the skilled artisan seeking to achieve a viable effervescent composition

that can be dissolve in water, which is Xiong et al.'s desire, would not look to Murpani et al. and further would view Murpani et al. as teaching away from utilizing an effervescent tablet as a dosage form.

Murpani et al. are further deficient in that they do not teach or suggest that sorbitol would be suitable for use in the effervescent green tea formulations that are the focus of Xiong et al. Murpani et al. also do not direct the skilled artisan to combine green tea extract, cranberry extract and sorbitol in an effervescent composition. To attempt to arrive at the tablet of claim 11 from Murpani et al. and Xiong et al., the skilled artisan would have to decide to include a filler in the effervescent composition of Xiong et al., when neither Xiong et al. nor Murpani et al. teach or suggest utilizing a filler in an effervescent formulation that also includes green tea extract. Moreover, Murpani et al. disclose that the filler is to add bulk to their COX-2 inhibitor composition. Neither Murpani et al. nor Xiong et al. teach or suggest that it is desirable to add bulk to a green tea effervescent formulation. The skilled artisan would then have to select sorbitol from a list of more than twenty-nine fillers identified by Murpani et al. when Murpani et al. ascribe no particular import to sorbitol, do not distinguish sorbitol over any of the other fillers listed, and expressly identify mannitol as a preferred filler. Furthermore, neither Murpani et al. nor Xiong et al. teach or suggest that it is desirable to utilize sorbitol in combination with a green tea extract. Therefore, the skilled artisan would have no reason to make the particular selections necessary to attempt to arrive at the tablet of claim 11. Accordingly, the rejection of claim 11 under 35 U.S.C. § 103 over Xiong et al. and further in view of Murpani et al. has been overcome, and Applicants respectfully request that it be withdrawn.

Claim 12 depends from claim 1 and specifies that the binder includes from 20 % by weight to 25 % by weight sorbitol. The discussion of the deficiencies of Xiong et al. and Murpani et al. set forth above with respect to claims 1 and 11 are incorporated herein. As established above with respect to claim 1, Xiong et al. fails to teach or suggest a tablet that includes an effervescent composition that includes at least 200 milligrams of cranberry extract.

Murpani et al. do not cure the deficiencies of Xiong et al. Nowhere in Murpani et al. is there a mention of cranberry extract. In addition, Murpani et al. do not teach or

suggest including cranberry extract in an effervescent composition. Murpani et al. also do not teach or suggest including from 20 % by weight to 25 % by weight sorbitol in an effervescent composition --let alone combining from 20 % by weight to 25 % by weight sorbitol in a composition that includes green tea extract such as the one in Xiong et al. Murpani et al. include sorbitol in a list of more than twenty-nine fillers. Nothing in Murpani et al. directs the skilled artisan to select sorbitol from among the many listed fillers. Moreover, Murpani et al. disclose that the effective amount of filler is from about 10 to 95 weight percent, preferably about 25 to about 85 weight percent, and most preferably about 80 weight percent of their composition, which, as stated previously, disintegrates in the mouth and is not an effervescent composition. Murpani et al. do not teach or suggest how much sorbitol should be included in an effervescent composition and further fail to direct the skilled artisan to include from 20 % by weight to 25 % by weight sorbitol in an effervescent composition. To arrive at such a composition would require hindsight reconstruction, which has been repeatedly established by legal precedent as impermissible. Murpani et al. thus fail to provide the requisite reason or motivation to the skilled artisan to modify the effervescent composition of Xiong et al. Applicants submit, therefore, that the rejection of claim 12 under 35 U.S.C. § 103 over Xiong et al. and further in view of Murpani et al. is unwarranted and respectfully request that it be withdrawn.

Claim 14 is directed to the tablet of claim 1 and further includes magnesium hydroxide. Neither Xiong et al. nor Murpani et al. teach magnesium hydroxide. Murpani et al. disclose a list of fillers. Included in this list of fillers is aluminum magnesium hydroxide. Aluminum magnesium hydroxide is not magnesium hydroxide. Moreover, nothing in Murpani et al. specifically directs the skilled artisan to select magnesium hydroxide from their list of twenty-nine fillers and include it in a tablet that includes an effervescent composition that also includes cranberry extract. To arrive at such a composition would require hindsight reconstruction, which is impermissible under existing legal precedent. Applicants submit, therefore, that the rejection of claim 14 under 35 U.S.C. § 103 over Xiong et al. and further in view of Murpani et al. is unwarranted and respectfully request that it be withdrawn.

Claims 1-10, 13, 15, 16, 18 and 31 stand rejected under 35 U.S.C. § 103 over U.S. Patent 6,231,866 ("Mann") in view of Xiong et al.

Mann discloses a dietary supplement produced by infusing plant-derived fiber with juice concentrate and drying the fiber (Mann, col. 3, lines 49-52). Mann refers to "plant-derived fiber" as "pomace" throughout his application (see, *Id.*, lines 52-55). Mann also describes a tablet that includes cranberry pomace. According to Mann, the fiber portion of his product (i.e., the pomace) is insoluble (*Id.*, col. 5, lines 50-51).

The discussion of Xiong et al. set forth above is incorporated herein by reference.

Claim 1 is now directed to a tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent that includes an acid and a base, binder and lubricant, and disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to a solution that is free of granules and particles. To establish a *prima facie* case of obviousness based upon a proposed combination of references there must be a reason in the prior art to combine the references. See, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. _____ (2007). Evidence of a reason to combine can be found if there is a teaching, suggestion or motivation in the prior art for making the proposed combination. See, M.P.E.P. 2142; *Fromson v. Anitec Printing Plates, Inc.*, 132 F.3d 1437 (Fed. Cir. 1997); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, (Fed. Cir. 1998). The reason, teaching, suggestion or motivation to make the claimed combination must be found in the prior art and must not be based on Appellants' disclosure. See, M.P.E.P. 2142. Here no such reason, teaching, suggestion or motivation exists. Mann describes a dried formulation that includes pomace, i.e., plant derived fiber, infused with a cranberry juice concentrate. Pomace is the pulpy residue that remains after crushing and pressing a fruit. Mann achieves his dried formulation by removing the juice from the pomace, concentrating the juice and then reuniting the juice with the pomace (Mann, col. 6, lines 28-31). Mann expressly discloses that the fiber portion of his formulation is insoluble. In particular, Mann discloses,

> Because the bioactive ingredients are infused into a generally fiber matrix, the bioactive components are shielded from degradation during transit through the stomach, thereby delivering a maximum concentration of bioactive ingredients in the intestines. The natural pectin components of the product slow down the

digestive process in the intestines and provide a natural sustained release of the active compounds from the fiber matrix, thereby enhancing the bioavailability of the active compounds. The insoluble fiber portion, while ingestible, serves as a bulking agent to promote regularity and good intestinal health and functioning. Mann, col. 5, lines 42-53.

Xiong et al. seek to achieve a water soluble formulation (Xiong et al, col. 3, line 29). Xiong et al. emphasize the importance of water solubility (see, *Id.*, Abstract and col. 3, lines 38-41). Xiong et al. also seek to provide a formulation that increases the formulation's absorption rate and therefore bioavailablility (*Id.*, col. 2, lines 62-65). Xiong et al. explain that by allowing the formulation to become disbursed or dissolved in water, the extracts are unlocked and become more available to the body upon consumption and that the effervescent action further agitates and unlocks the beneficial extracts contained therein (*Id.*, col. 3, lines 36-43). The formulation of Mann, in contrast, is not water soluble. Mann expressly states that his formulation includes a water insoluble fiber portion (Mann, col. 5, lines 50-51). Xiong et al. do not teach or suggest including a water insoluble component in an effervescent composition --let alone including pomace in an effervescent composition. Therefore, the skilled artisan, familiar with Mann, would have no reason to look to Xiong et al., and further would have no reason to formulate the juice concentrate infused fiber product of Mann as an effervescent composition.

The proposed combination of Mann and Xiong et al. is further deficient for at least the following additional reasons. Xiong et al. disclose that the effervescent action of an effervescent composition further agitates and unlocks the beneficial extracts contained therein. Xiong et al. thus seek to increase the bioavailability of their extracts by creating an effervescent composition that unlocks the extracts prior to their entering the body. The purpose of Mann, in contrast, is to increase bioavailability by maintaining the juice concentrate intact until after it has passed through the stomach. Therefore, formulating the juice concentrate infused fiber product of Mann as an effervescent composition would defeat the purpose of Mann. Moreover, neither Xiong et al. nor Mann teaches or suggests that the fiber portion will remain intact or will be able to function as intended if subjected to effervescent action of an effervescent couple. Accordingly, the skilled artisan would

have no reason to believe that formulating the fiber product of Mann as an effervescent composition would enable Mann to achieve his goals. For at least these additional reasons, the skilled artisan would not think to formulate Mann's fiber product as an effervescent composition and further would refrain from doing so.

The proposed combination of Mann and Xiong et al. is further deficient because Xiong et al. do not teach or suggest how to formulate the fiber product of Mann as an effervescent composition such that it will disintegrate in water having a temperature of about 22°C in less than 2.5 minutes to a solution that is free of granules and particles. Examples 2 and 3 of the above-captioned application demonstrate that when CRANMAX was formulated in an effervescent composition and placed in water, granules were observed. Therefore, the proposed combination of Mann and Xiong et al. also fails to enable the effervescent tablet of claim 1. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Mann in view of Xiong et al. has been overcome and respectfully request that it be withdrawn.

Claims 2-10, 13, 15, 16, 18 and 31 are distinguishable under 35 U.S.C. § 103 over Mann in view of Xiong et al. for at least the reasons set forth above in distinguishing claim 1.

Claim 16 is further distinguishable under 35 U.S.C. § 103 over Mann in view of Xiong et al. for at least the following additional reasons. Claim 16 is directed to a tablet that includes an effervescent composition that includes from 50 mg to 200 mg cranberry seed oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 5 kilopounds and disintegrating in water in less than 2.5 minutes. Nowhere in Mann is there a teaching or a suggestion of cranberry seed oil –let alone including from 50 mg to 200 mg cranberry seed oil in an effervescent composition. Although Mann discloses that, in general, oil can be extracted from a plant, Mann does not teach cranberry seed oil. Rather, when Mann discuses oil, he does so with respect to saw palmetto oil.

Xiong et al. also do not teach or suggest cranberry seed oil –let alone including from 50 mg to 200 mg cranberry seed oil in an effervescent composition. Rather, Xiong et al. disclose that their formulations can include fruit extract (see, Xiong et al., col. 3, lines 7-10, and Example 7). At no point do Xiong et al. teach or suggest that the fruit

extract can be cranberry seed oil. As such, Mann and Xiong et al. fail to teach or suggest each and every element of claim 16. Accordingly, a *prima facie* case of the obviousness of claim 16 has not been made, and the rejection of claim 16 under 35 U.S.C. § 103 over Mann in view of Xiong et al. cannot stand. Should this rejection be maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Mann or Xiong et al. of a teaching of cranberry seed oil.

Claim 31 also is further distinguishable under 35 U.S.C. § 103 over Mann in view of Xiong et al. for at least the following additional reasons. Claim 31 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent comprising an acid and a base, binder, and lubricant, the binder being present in the composition in amount of from about 15 % by weight to about 50 % by weight, and the tablet being free of picking, capping, die wall etching and lamination. Mann does not mention binders and further fails to teach or suggest including from about 15 % by weight to about 50 % by weight binder in an effervescent tablet.

Xiong et al. disclose that polyvinyl pyrrolidone is one example of a binder. In each of the Example formulations of Xiong et al. the range of binder is indicated as being from 1 to 10 (%w/w). Nowhere in Xiong et al. is there a teaching of including from about 15 % by weight to about 50 % by weight binder in an effervescent tablet. As such, the proposed combination fails to teach or suggest a required element of claim 31. Accordingly, a *prima facie* case of obviousness has not been made, and the rejection of claim 31 under 35 U.S.C. § 103 over Mann in view of Xiong et al. must be withdrawn.

Claims 11 and 12 stand rejected under 35 U.S.C. § 103 over Mann and Xiong et al. as applied to claims 1-10, 13, 15-18 and 31 above, and further in view of Murpani et al.

The discussion of the disclosures of Mann and Xiong et al. set forth above are incorporated herein.

Murpani et al. disclose a fast dissolving tablet that disintegrates quickly in the mouth and includes a therapeutically effective amount of a drug that acts selectively as a clycooxgenase-2 (COX-2) enzyme inhibitor (Murpani et al., Abstract).

Claim 11 depends from claim 1 and specifies that the effervescent agent includes sodium bicarbonate and citric acid and that the tablet further includes polyethylene glycol, sorbitol and sodium benzoate. The discussion of the deficiencies of the proposed combination of Mann and Xiong et al., set forth above, are incorporated herein. As established above with respect to claim 1, the proposed combination of Mann and Xiong et al. fails to teach or suggest a tablet that includes an effervescent composition that includes at least 200 milligrams of cranberry extract.

Murpani et al. do not cure the deficiencies of the proposed combination of Mann and Xiong et al. Murpani et al. do not teach or suggest anything about cranberry extract or the amount of cranberry extract to include in an effervescent composition. Murpani et al. also do not teach or suggest combining sorbitol with a green tea extract such as the one disclosed in Xiong et al. Moreover, the skilled artisan is not an automaton (see, *KSR Int'l Co. v. Teleflex Inc.*, 500 U.S. _____, 82 U.S.P.Q.2d 1385 (2007)). The technology described in Murpani et al. is directed to tablets that do not have to be dissolved in water. Murpani et al. expressly state that an object of their invention is to provide a fast dissolving tablet that disintegrates quickly in the mouth without the need for additional water (Murpani et al., page 1, para. [0007]). Murpani et al. further disclose that many elderly persons have difficulty in taking oral dosage forms such as solutions, suspensions, tablets and capsules because of hand tremors and dysphasia (*Id.*, page 1, para. [0005]). Murpani et al further disclose that the increase in intake of water for swallowing conventional dosage forms results in frequent urination and nocturia (*Id.*, page 1). Murpani et al. also note that swallowing problems are also common in the mentally ill, the developmentally disabled, and patients who are uncooperative, on reduced liquid-intake plans or are nauseated (*Id.*, para. [0006]). Thus, Murpani et al. provide the skilled artisan with no reason to formulate a composition into an effervescent dosage form that dissolves in water such as the one in Xiong et al., and further teach away from utilizing an effervescent tablet as a dosage form. Murpani et al. also fail to direct the skilled artisan to combine cranberry extract, sodium bicarbonate, citric acid, polyethylene glycol, sorbitol and sodium benzoate to form an effervescent composition. Therefore the skilled artisan would have no reason to do so.

Moreover, to arrive at the tablet of claim 11 from the proposed combination of Mann, Xiong et al. and Murpani et al., the skilled artisan would have to make a series of selections. In particular, the skilled artisan would have to 1) decide to formulate an infused fiber product with cranberry extract when Mann disclose that the fiber product can be infused with any one of a number of fruit, vegetable, seed and herb juices, 2) select at least 200 milligrams of cranberry extract, 3) decide to look to Xiong et al., which expressly describe water soluble compositions, when Mann expressly discloses that his infused fiber product includes insoluble fiber, 4) decide to formulate the infused fiber product of Mann as an effervescent composition when Mann expressly discloses that the fiber product allows the concentrate to pass through the stomach intact, and Xiong et al. expressly disclose that effervescent formulas assist in breaking up components contained therein to increase their bioavailability, 5) decide to look to Murpani et al., which is focused on a tablet that rapidly dissolves and disintegrates in the mouth, when Xiong et al. disclose that an object of their invention is to provide a product that is capable of being administered in a liquid form and that their formulation is used by dispensing it in water, and further in light of the fact that Mann seeks to maintain his concentrate intact through passage through the stomach, 6) decide to include a filler, when Murpani et al. do not teach or suggest utilizing a filler in an effervescent formulation that also includes green tea extract such as the one of Xiong et al., and then 7) select sorbitol from a list of more than twenty-nine fillers identified by Murpani et al., when Murpani et al. ascribe no particular import to sorbitol, do not distinguish sorbitol over any other filler, and express a preference for mannitol. There is nothing in the proposed combination of Mann, Xiong et al. or Murpani et al. that directs the skilled artisan to make these particular selections, and, as noted above, there are a number of passages that teach away from making the requisite selections. Applicants submit, therefore, that the rejection of claim 11 under 35 U.S.C. § 103 over Mann and Xiong et al. and further in view of Murpani et al. is unwarranted and respectfully request that it be withdrawn.

Claim 12 depends from claim 1 and specifies that the binder includes from 20 % by weight to 25 % by weight sorbitol. The discussion of the deficiencies of the proposed combination of Mann and Xiong et al. set forth above with respect to claim 1 are incorporated herein. As established above with respect to claim 1, the proposed

combination of Mann and Xiong et al. fails to teach or suggest a tablet that includes an effervescent composition that includes at least 200 milligrams of cranberry extract.

Murpani et al. do not cure the deficiencies of the proposed combination of Mann and Xiong et al. Murpani et al. also do not teach or suggest including from 20 % by weight to 25 % by weight sorbitol in an effervescent composition. To the contrary, Murpani et al. include sorbitol in a list of more than 29 other fillers. Nothing in Murpani et al. directs the skilled artisan to select sorbitol from among the many listed fillers. Rather, Murpani et al. express a preference for mannitol. Moreover, Murpani et al. disclose that the effective amount of filler is from about 10 to 95 weight percent, preferably about 25 to about 85 weight percent, and most preferably about 80 weight percent of their composition, which, as stated previously, disintegrates in the mouth. Murpani et al. do not teach or suggest how much sorbitol should be included in an effervescent composition that is intended to be dissolved in water such as the one of Xiong et al. Moreover, nothing in Murpani et al. directs the skilled artisan to select sorbitol and then include in an effervescent composition in an amount from 20 % by weight to 25 % by weight sorbitol. To arrive at such a composition would require hindsight reconstruction, which has been repeatedly established by legal precedent as impermissible. Applicants submit, therefore, that the rejection of claim 12 under 35 U.S.C. § 103 over Mann and Xiong et al. and further in view of Murpani et al. is unwarranted and respectfully request that it be withdrawn.

The claims now pending in the application are in condition for allowance and such action is respectfully requested. The Examiner is invited to telephone the undersigned should a teleconference interview facilitate prosecution of this application.

Please charge any additional fees owing or credit any over payments made to Deposit Account No. 501,171.

Respectfully submitted,

Date: January 2, 2008

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